

this section may be safely used as components of articles intended for use in contact with food subject to the provisions of this section.

(a) *Identity.* For the purposes of this section, ethylene-carbon monoxide copolymers (CAS Reg. No. 25052-62-4) consist of the basic polymers produced by the copolymerization of ethylene and carbon monoxide such that the copolymers contain not more than 30 weight-percent of polymer units derived from carbon monoxide.

(b) *Conditions of use.* (1) The polymers may be safely used as components of the food-contact or interior core layer of multilaminate food-contact articles.

(2) The polymers may be safely used as food-contact materials at temperatures not to exceed 121 °C (250 °F).

(c) *Specifications.* (1) Food-contact layers formed from the basic copolymer identified in paragraph (a) of this section shall be limited to a thickness of not more than 0.01 centimeter (0.004 inch).

(2) The copolymers identified in paragraph (a) of this section shall have a melt index not greater than 500 as determined by ASTM method D1238-82, condition E “Standard Test Method for Flow Rates of Thermoplastics by Extrusion Plastometer,” which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(3) The basic copolymer identified in paragraph (a) of this section, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use, as determined from tables 1 and 2 of §176.170(c) of this chapter, yields net chloroform-soluble extractives in each extracting solvent not to exceed 0.5 milligram per square inch of food-contact surface when tested by methods described in §176.170(d) of this chapter.

(4) The provisions of this section are not applicable to ethylene-carbon monoxide copolymers complying with §175.105 of this chapter.

[57 FR 32422, July 22, 1992]

**§ 177.1315 Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymers.**

Ethylene-1, 4-cyclohexylene dimethylene terephthalate copolymer may be safely used as articles or components of articles intended for use in contact with food subject to provisions of this section and of part 174 of this chapter.

(a) *Identity.* For the purposes of this section, ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers (1,4-benzene dicarboxylic acid, dimethyl ester, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25640-14-6) or (1,4-benzenedicarboxylic acid, polymerized with 1,4-cyclohexanedimethanol and 1,2-ethanediol) (CAS Reg. No. 25038-91-9) are basic copolymers meeting the specifications prescribed in paragraph (b) of this section, to which may have been added certain optional substances required in their production or added to impart desired physical or technical properties.

(b) *Specifications:*

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
1. <i>Non-oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 66 mole percent of ethylene glycol and 1 to 34 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).	Inherent viscosity of a 0.50 percent solution of the copolymer in phenol-tetrachloroethane (60:40 ratio wt/wt) solvent is not less than 0.669 as determined by using a Wagner viscometer (or equivalent) and calculated from the following equation: Inherent viscosity = (Natural logarithm of $N_r/c$ ) where: $N_r$ =Ratio of flow time of the polymer solution to that of the solvent, and $c$ =concentration of the test solution expressed in grams per 100 milliliters.	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with water added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	No test required ...	In contact with foods, including foods containing not more than 25 percent (by volume) aqueous alcohol, excluding carbonated beverages and beer. Conditions of hot fill not to exceed 82.2 °C (180 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.
.....do .....	.....do .....	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface when extracted with 3 percent (by volume) aqueous acetic acid added at 82.2 °C (180 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	.....do .....	Do.
.....do .....	.....do .....	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.	.....do .....	Do.
.....do .....	.....do .....	(4) 0.16 microgram per square centimeter (1.0 microgram per square inch) of food-contact surface when extracted for 24 hours with 25 percent (by volume) aqueous ethanol at 48.9 °C (120 °F).	.....do .....	Do.

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
2. <i>Oriented</i> ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 85 mole percent ethylene glycol and 1 to 15 mole percent of 1,4-cyclohexane-dimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).	.....do .....	(1) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of the oriented copolymer when extracted with water added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	When extracted with heptane at 65.6 °C (150 °F) for 2 hours: terephthaloyl moieties do not exceed 0.09 microgram per square centimeter (0.60 microgram per square inch) of food-contact surface.	In contact with non-alcoholic foods including carbonated beverages. Conditions of hot fill not exceeding 87.8 °C (190 °F), storage at temperatures not in excess of 48.9 °C (120 °F). No thermal treatment in the container.
	.....do .....	(2) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 3 percent (by volume) aqueous acetic acid added at 87.8 °C (190 °F) and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	.....do .....	Do.
	.....do .....	(3) 0.08 microgram per square centimeter (0.5 microgram per square inch) of food-contact surface of oriented copolymer when extracted for 2 hours with <i>n</i> -heptane at 48.9 °C (120 °F). The heptane extractable results are to be divided by a factor of 5.	.....do .....	Do.
	.....do .....	(4) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 20 percent (by volume) aqueous ethanol heated to 65.6 °C (150 °F) for 20 minutes and allowed to cool to 48.9 °C (120 °F) in contact with the food-contact article.	.....do .....	In contact with foods and beverages containing up to 20 percent (by volume) alcohol. Conditions of thermal treatment in the container not exceeding 65.6 °C (150 °F) for 20 minutes. Storage at temperatures not in excess of 48.9 °C (120 °F).
	.....do .....	(5) 0.23 microgram per square centimeter (1.5 micrograms per square inch) of food-contact surface of oriented copolymer when extracted with 50 percent (by volume) aqueous ethanol at 48.9 °C (120 °F) for 24 hours.	.....do .....	In contact with foods and beverages containing up to 50 percent (by volume) alcohol. Conditions of fill and storage not exceeding 48.9 °C (120 °F). No thermal treatment in the container.

Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymers	Inherent viscosity	Maximum extractable fractions of the copolymer in the finished form at specified temperatures and times (expressed in micrograms of the terephthaloyl moieties/square centimeter of food-contact surface)	Test for orientability	Conditions of use
3. Ethylene-1,4-cyclohexylene dimethylene terephthalate copolymer is the reaction product of dimethyl terephthalate or terephthalic acid with a mixture containing 99 to 95 mole percent of ethylene glycol and 1 to 5 mole percent of 1,4-cyclohexanedimethanol (70 percent <i>trans</i> isomer, 30 percent <i>cis</i> isomer).	No test required ...	For each corresponding condition of use, must meet specifications described in § 177.1630(f), (g), (h), or (j).	No test required ...	For each corresponding specification, may be used as a base sheet and base polymer in accordance with conditions of use described in § 177.1630(f), (g), (h), or (j).

(c) *Analytical method for determination of extractability.* The total extracted terephthaloyl moieties can be determined in the extracts, without evaporation of the solvent, by measuring the ultraviolet (UV) absorbance at 240 nanometers. The spectrophotometer (Varian 635-D, or equivalent) is zeroed with a sample of the solvent taken from the same lot used in the extraction tests. The concentration of the total terephthaloyl moieties in water, 3 percent acetic acid, and in 8 percent aqueous alcohol is calculated as bis(2-hydroxyethyl terephthalate) by reference to standards prepared in the appropriate solvent. Concentration of the terephthaloyl moieties in heptane is calculated as cyclic trimer (C<sub>6</sub>H<sub>4</sub>CO<sub>2</sub>C<sub>2</sub>H<sub>4</sub>CO<sub>2</sub>)<sub>3</sub>, by reference to standards prepared in 95:5 percent (v/v) heptane: tetrahydrofuran.

[45 FR 39252, June 10, 1980, as amended at 47 FR 24288, June 4, 1982; 49 FR 25629, June 22, 1984; 51 FR 22929, June 24, 1986; 60 FR 57926, Nov. 24, 1995]

#### § 177.1320 Ethylene-ethyl acrylate copolymers.

Ethylene-ethyl acrylate copolymers may be safely used to produce packaging materials, containers, and equipment intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance

with the following prescribed conditions:

(a) Ethylene-ethyl acrylate copolymers consist of basic resins produced by the catalytic copolymerization of ethylene and ethyl acrylate, to which may have been added certain optional substances to impart desired technological properties to the resin. Subject to any limitations prescribed in this section, the optional substances may include:

(1) Substances generally recognized as safe in food and food packaging.

(2) Substances the use of which is permitted under applicable regulations in parts 170 through 189 of this chapter, prior sanction, or approvals.

(b) The ethyl acrylate content of the copolymer does not exceed 8 percent by weight unless it is blended with polyethylene or with one or more olefin copolymers complying with § 177.1520 or with a mixture of polyethylene and one or more olefin copolymers, in such proportions that the ethyl acrylate content of the blend does not exceed 8 percent by weight, or unless it is used in a coating complying with § 175.300 or § 176.170 of this chapter, in such proportions that the ethyl acrylate content does not exceed 8 percent by weight of the finished coating.

(c) Ethylene-ethyl acrylate copolymers or the blend shall conform to the specifications prescribed in paragraph (c)(1) of this section and shall meet the